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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

NEKTAR THERAPEUTICS, Plaintiff/Counter-Defendant, v. ELI LILLY & CO., Defendant/Counter-Claimant.	CASE NO. 3:23-CV-03943-JD **DEFENDANT'S TRIAL BRIEF**

I. INTRODUCTION

In 2017, Nektar and Lilly entered into a License Agreement for the development of an investigational compound, Rezpeg. ECF 210-2. Lilly conducted seven clinical trials across five years "[redacted]" for conditions including atopic dermatitis and lupus. ECF 210-7 ¶71. Despite Lilly's investment of [redacted] and years of efforts, Rezpeg did not yield acceptable clinical trial results according to the standards that Nektar and Lilly jointly developed and agreed to. Dissatisfied with the natural consequences of those results—the same results that befall the vast majority of investigational compounds that proceed to clinical testing—Nektar requested that Lilly voluntarily terminate the Agreement and "[redacted]" so that Nektar could continue Rezpeg's development without Lilly's participation. ECF 210-3 at 140:20-24, 143:21-144:1. Lilly complied. As a result, Nektar retained Lilly's initial $150 million payment, benefitted from the additional [redacted] Lilly had invested in development, and regained full rights to 100% of Rezpeg and any potential future profits. ECF 210-7 at ¶86; *accord* ECF 210-3 at 67:24-68:5, 79:6-10, 152:6-10, 168:22-25; ECF 210-43 at 281:16-20, 283:2-6, 299:4-10.

Nektar then sued Lilly for breach of the License Agreement. Nektar alleges that Lilly breached the Agreement by failing to use Commercially Reasonable Efforts ("CRE") to develop Rezpeg—even though that provision does not permit post-hoc second guessing of ordinary course judgment calls inherent to the clinical trial process (all that Nektar points to here). Nektar also criticizes the sophisticated clinical trial process that the parties jointly executed by claiming breach of a Good Research Practices schedule to the Agreement—even though that schedule imposes obligations only on Nektar, not Lilly. ECF 210-2 at §4.8 Sched. 4.8. And Nektar complains that Lilly breached a provision requiring reasonable cooperation in the transfer of materials necessary or useful to Rezpeg's development, despite failing to identify any materials that Lilly supposedly withheld from Nektar or any damages. For this, Nektar intends to ask the jury for a $1 billion damages award. Trial will show that each of Nektar's claims fail.

II. NEKTAR CANNOT PROVE BREACH OR CAUSALLY RELATED DAMAGES FOR ITS CRE CLAIMS.

Nektar cannot meet its "burden to prove" that Lilly (i) breached the License Agreement, or (ii) "damages suffered by [Plaintiff] as a result of the breach"—dispositive elements of Nektar's breach of contract claim. *Glob. BTG LLC v. Nat'l Air Cargo, Inc.*, 650 F. App'x 303, 306 (9th Cir. 2016). The Agreement required Lilly to use CRE, defined as "effort, expertise and resources normally used by [Lilly] in the development and/or commercialization of a comparable pharmaceutical product Controlled by [Lilly] which is … at a similar stage of development," and "determined on an Indication-by-Indication and country-by-country basis." ECF 210-2 at 4-5. Nektar alleges that Lilly breached the Agreement by failing to use CRE "in designing and conducting the[] studies, in developing Rezpeg, and in bringing it to market." ECF 61 at ¶86. Specifically, Nektar claims Lilly failed to use CRE in developing Rezpeg for treatment of atopic dermatitis or lupus. Lilly will demonstrate at trial that there was no breach, as Lilly did use CRE with respect to all aspects of Rezpeg's development, and that Nektar suffered no causally related damages.

A. Atopic Dermatitis CRE Claims Fail for Lack of Breach

Nektar cannot prove that Lilly failed to expend appropriate "effort, expertise, and resources" regarding Rezpeg for the treatment of atopic dermatitis.

1. Lilly's Solicitation and Evaluation of ISRs Was Not a Breach

Nektar claims that "Lilly breached its CRE obligation by deviating from its [redacted] to delay Rezpeg's eczema development." ECF 228-1 at 15. Not so. Lilly collected information about ISRs [redacted] and Nektar cannot identify a comparator where Lilly disregarded similar direction. ECF 210-30.

The evidence will show that Rezpeg's ISRs were a significant hurdle to Rezpeg's success, and that Lilly invested substantial effort to try to overcome that hurdle. Trials confirmed previous data that Rezpeg caused frequent ISRs [redacted] ECF 210-20; ECF 210-21 at 3-4; ECF 210-22 at 3; ECF 210-23 at 3. As Nektar later told the FDA, ISRs were "[redacted]." ECF 210-24 at 3. Some patients experienced prominent "[redacted]" sized reactions that lasted for weeks, often

until the patient's "[redacted]." ECF 210-25 at 86:14-87:6; ECF 210-27 at 3. Nektar internally recognized that ISRs constituted [redacted]. ECF 210-32 at 4. Lilly thoroughly evaluated multiple potential solutions. ECF 210-29 at 205:2-9. For example, Lilly conducted clinical studies examining whether topical steroids or oral antihistamines mitigated ISRs, [redacted]. ECF 210-33 at 4; ECF 210-34 at 3-4; ECF 210-36 at 4-5. And other efforts to explore variations in the [redacted]. ECF 210-38 at 3. It was not a breach of Lilly's CRE obligation for Lilly to repeatedly try to solve a problem that all agree posed (and continues to pose) challenges to Rezpeg's commercialization. ECF 210-29 at 87:6-89:1, 159:22-160:1.

2. Lilly's Clinical Trial Redesign Was Not a Breach

Nektar alleges that Lilly breached its CRE obligations by redesigning a Rezpeg phase 2 study to focus on bio-experienced patients, meaning patients with prior exposure to other treatments. ECF 228-1 at 10. Lilly believed that bio-experienced patients were important because Rezpeg's ISR problems meant that it was a dubious candidate for use as a first-line treatment for skin conditions like atopic dermatitis. Patients "[redacted]," ECF 210-50 at 163:23-164:19, particularly when they already had other effective first-line atopic dermatitis treatment options available, such as Dupixent, which does not have the same risk of ISRs. Given these realities, Lilly believed Rezpeg was most promising as a second-line treatment for patients who had tried Dupixent but were unsatisfied and looking for a second option—i.e., "[redacted]" patients for whom "[redacted]" ECF 210-49 at 4; ECF 210-53 at 3-4.

Nothing about that reasonable, clinically-driven judgment breached any CRE obligations. In reality, it was Lilly's standard operating procedure to [redacted]. ECF 210-7 at 212:8-18; ECF 210-58 at 4. Lilly developed a new study design and Nektar approved of the design, including the proportion of bio-experienced and bio-naïve patients, recognizing that "[redacted]" is a matter of "[redacted]." ECF 210-54 at 2 (emphasis added). In other words, this was a matter of judgment, not effort, expertise, or resources. Additionally, any suggestion that the decision to focus on

bio-experienced patients breached Lilly's CRE obligations will fail because there is no evidence that Lilly's strategy for Rezpeg fell short of Lilly's strategy for a "comparable pharmaceutical product" for an atopic dermatitis indication. ECF 210-2 at 4-5.

3. Lilly's Decision to Include Interim Analyses Was Not a Breach

Nektar also claims that Lilly breached its CRE obligations by including "interim analyses in Rezpeg's Phase 2 eczema study design." ECF 228-1 at 10. Not true. Lilly prepared an initial plan to perform periodic evaluations of clinical trial data throughout the study. When Nektar raised its objections to Lilly's initial interim-analysis plan, Lilly agreed, [redacted] and decide upon a new plan acceptable to both parties. ECF 210-60 at 3. After extensive discussions, the parties [redacted]. ECF 210-8 at 273:9-19.

That is no different from how Lilly treated similar compounds. Lilly proposed similar interim analyses for another potential atopic dermatitis treatment (CD200R). ECF 210-29 at 253:21-254:24, 258:22-259:5 ([redacted]).

4. Nektar's Allegations that Lilly "Rethought" Rezpeg Was Not a Breach

Nektar alleges that Lilly's "rethink" of Rezpeg for atopic dermatitis was a breach of its CRE obligations. ECF 228-1 at 9. But careful consideration of the best development path forward is not a lack of efforts. Nothing in the CRE provision prevents Lilly from actively evaluating, incorporating, and responding to new data in designing multimillion-dollar trials; rather, that is Lilly's usual practice. And contrary to Nektar's claims, Lilly never attempted to sabotage Rezpeg's development in atopic dermatitis in order to favor any of its other products, including Lebrikizumab ("Lebri") and CD200R. In fact, Lilly often evaluates multiple assets for the same indication, and even tested two other atopic dermatitis assets apart from Lebri and CD200R following Rezpeg's phase 1 trial. *See* ECF 207-2, Ex. A at 86. Regardless, even if Lilly had decided to evaluate Rezpeg against other molecules, it was entitled to do so under the parties' CRE clause. ECF No. 210-2 at 4-5.

5. The Calculation of Phase 1 Exploratory Endpoints Was Not A Breach

Nektar claims that over the six-year period that Lilly worked to develop Rezpeg, through seven clinical trials, one of its subcontractors made a single math error that Lilly failed to catch at the time. Specifically, the subcontractor miscalculated data regarding Rezpeg's efficacy for treating eczema. This was not a breach by Lilly either. The subcontractor who committed the underlying mistake is one that [redacted]. ECF 210-5 at 77:7-15; ECF 210-66 at 83:13-20. Indeed, Nektar thought that the subcontractor was "[redacted]" and was "[redacted]" in the past. ECF 210-5 at 79:15-18, 106:21-107:2. Nektar concedes that Lilly—at worst—"[redacted]" ECF 228-1 at 12. Nothing in the CRE provision guarantees that Lilly's subcontractors will never make mistakes or that Lilly will catch 100% of mistakes. The CRE provision simply requires Lilly to use reasonable "effort[s], expertise or resources," which Lilly did. ECF 210-2 at 4. And in any event the mistake had no impact on Rezpeg's development, as even with the error, Rezpeg met the bar for further development for atopic dermatitis. *See* ECF 81-1 at 9 (Nektar explains that "we already have proof of concept in [the AtD] Phase Ib trial").

Nektar also alleges that Lilly failed to use experienced statisticians in supervising the subcontractor. But the relevant personnel were highly qualified. For example, one of the statisticians (Heng Zou) has over 23 years of clinical experience over 45 trials. ECF 210-64 at 96:7-10, 272:18-276:23, 278:24-279:8. These same statisticians worked on multiple other early-phase Lilly assets, including CD200R, and Lilly continued to entrust them with overseeing the statistical analysis of its clinical trials following the mistake. ECF 210-63 at 68:21-69:8; ECF 210-64 at 17:19-18:1, 51:22-52:6.

B. Lupus CRE Claims Fail for Lack of Breach

Nektar cannot prove that Lilly failed to expend appropriate "effort, expertise, and resources" regarding the development of Rezpeg for the treatment of lupus. ECF 210-2 at 4.

1. Lilly Did Not Breach by Stopping Clinical Development of Rezpeg for Lupus

Nektar alleges that Lilly breached its CRE obligations when it "quick[ly]" decided not to continue development of Rezpeg for lupus after Rezpeg failed its Phase 2 trial. *See* ECF 228-1 at 14-15 ("Lilly's Quick Kill"). Not so. Lilly has never advanced a lupus treatment to Phase 3 after failing the Phase 2

endpoints, and Rezpeg was no different. ECF 210-11 at 5. The parties agreed that the Phase 2 trial would include a primary endpoint that would measure the reduction of lupus activity using an index known as SLEDAI- 4, along with secondary endpoint measures based on indexes known as SRI-4 and BICLA. ECF 210-7 ¶76. Together, the parties determined critical success factors ("CSF") based on SRI-4 and BICLA, which established the results that were required for a "go" decision. ECF 210-10 at 6 [redacted] Subsequently, [redacted]. ECF 210-8 at 144:21-145:4; ECF 210-12; ECF 210-10 at 5-6. [redacted]. ECF 210-8 at 143:5-17, 144:17-20; ECF 210-46 at 3-4.

Ultimately, Rezpeg missed its primary endpoint, missed one CSF (SRI-4) for all three tested doses, and missed the other CSF (BICLA) on all but one dose. ECF 210-14; ECF 210-16. Accordingly, Lilly decided not to pursue Rezpeg's development for lupus. *Id.*

Independently, Nektar will not be able to prove a breach because it has not identified a comparator for which Lilly even allegedly expended greater effort, expertise, or resources. Nektar cannot identify any lupus product that missed its Phase 2 CSFs and primary endpoint, yet still proceeded to Phase 3. Lilly has high standards that it applies to all of its medicines and Rezpeg was no different.

2. Lilly Did Not Breach by Deciding Against Over-Enrolling the Phase 2 Lupus Studies

Although Nektar now claims that Lilly breached its CRE obligations by deciding not to over enroll a Phase 2 study, the evidence will show that Nektar "[redacted]" and concurred that "[redacted]" ECF 210-47 at 3; ECF 210-48 at 3. And just like its other claims, Nektar will be unable to provide any evidence that Lilly [redacted] in similar circumstances for other comparable medicines.

C. The CRE Claim Fails for Lack of Causally-Related Damages

Nektar cannot prove another of the "essential elements" of its claims: that any breach caused it damages. *R. Vig Props., v. Rahimzada*, 184 N.Y.S.3d 782, 786 (N.Y. App. Div. 2023) (internal citation omitted).

Nektar suffered no damages as a result of any of the alleged breaches. Nektar was only entitled to further payments under the Agreement if Rezpeg hit certain milestones during the parties' collaboration. ECF 210-2 §§6.2, 6.3. But Rezpeg never hit these milestones. Lilly terminated the contract—as it was expressly permitted to do— at Nektar's request before the first milestone (phase 3 trials). ECF 210-2 §11.2.

Unentitled to milestone payments, Nektar seeks to recover the profits that it claims it lost from an alleged delay in Rezpeg's development. However, the Agreement expressly precludes this type of award, too. Absent gross negligence or willful misconduct (nothing close to which is supported by the evidence), the parties unambiguously agreed that neither would be liable to the other "FOR REMOTE, SPECULATIVE, PUNITIVE OR EXEMPLARY, ***OR OTHER SPECIAL DAMAGES, INCLUDING LOST PROFITS***, ARISING OUT OF THIS AGREEMENT BASED ON CONTRACT, TORT OR ANY OTHER LEGAL THEORY." *Id.* §10.6 (emphasis added). Nektar knows it cannot recover lost profits, so it seeks the same thing by another name: the hypothetical reduction in Rezpeg's future returns.

Regardless of how Nektar describes this theory, it remains "a lost profits analysis." *Capstone Logistics Holdings, Inc. v. Navarrete*, 2018 WL 6786237, at *5 (S.D.N.Y. Dec. 13, 2018) (internal citation omitted); *see also That's What She Said, Inc. v. Gutter Games Ltd.*, 2024 WL 3678473, at *16-18 (S.D.N.Y. Aug. 5, 2024). For example, on a claim for breach of a contract to provide guard services to a warehouse, "general damages would be based on the difference between the contract price for the service and the going rate or market price for guard service." Dan B. Dobbs, Dobbs Law of Remedies § 12.2(3) (1993). "'Special' or 'consequential' damages, on the other hand, seek to compensate a plaintiff for additional losses (other than the value of the promised performance) that are incurred as a result of the defendant's breach," *Schonfeld*, 218 F.3d at 176, such as the value of the warehouse's contents if the watchman does not show and the warehouse burns down, Dobbs § 12.2(3). Here, direct damages would be Nektar's cost of finding substitute development services to make up for any purported shortfall in the "effort, expertise, and resources" that Lilly committed to delivering. But Nektar cannot prove such damages at trial. After all, its experts only purported to calculate the consequences of Lilly's alleged failure to use CRE, which, like the loss of the warehouse's contents in the watchman example, represent "special" or "consequential" damages. *E.g.*, *N. Am. Photon Infotech Ltd. v. ZoomInfo LLC*, 2021 WL

4482208, at *7 (S.D.N.Y. Sept. 30, 2021), *aff'd*, 2024 WL 4799843 (2d Cir. Nov. 15, 2024) (providing example that if contractual breach "incidentally led to the loss of a separate valuable supply agreement, the asset value of the supply agreement would be consequential damages").

III. NEKTAR CANNOT PROVE BREACH OR CAUSALLY RELATED DAMAGES FOR ITS GOOD RESEARCH PRACTICES CLAIMS.

Nektar alleges that Lilly breached Section 4.8 of the License Agreement by failing to use "Good Research Practices," "including 'qualified' personnel and proper data management and review practices." ECF 228 at 8. This theory of liability likewise fails. *First*, under Section 4.8 of the Agreement, only ***Nektar*** was required to follow the "Good Research Practices" schedule. ECF 210-2 §4.8. The Agreement imposes no contractual requirement for Lilly to do so. Given that limited and unilateral obligation imposed only on Nektar, ***Lilly's*** alleged noncompliance is not a breach. *Second*, even if Lilly had contractually agreed to follow the "Good Research Practices" schedule, there still would be no breach. The schedule states that "personnel" should be "qualified and can perform Study tasks to meet expectations." *Id.* Sch. 4.8. Lilly complied with those obligations by assigning personnel and contractors who were amply qualified. *Supra* II(A)(5). Further, any alleged violation of the Good Research Practices schedule had no impact on Rezpeg's development, and therefore caused no damages to Nektar.

IV. NEKTAR CANNOT PROVE BREACH OR CAUSALLY RELATED DAMAGES BASED ON A SUPPOSED FAILURE TO RETURN MATERIALS.

The Agreement required Lilly to "reasonably cooperate with Nektar to facilitate a smooth, orderly and [redacted] transition … of any ongoing Product development activities" and to "use Commercially Reasonable Efforts … with respect to any such ongoing Product development activities to [redacted] transfer" certain documents and "other materials or information necessary or useful for the continued development, manufacture and commercialization" of Rezpeg and "only to the extent that such … materials … relate solely and exclusively to" Rezpeg. ECF 210-2 §11.4(b)(ii). Lilly did just that. Lilly worked with Nektar to transfer the relevant materials within a reasonable timeframe and Nektar's claims that Lilly has still failed to adequately transfer unspecified "[redacted]" are baseless. ECF 228 at 25.

First, Nektar has identified nothing that is presently missing. In fact, [redacted]. *Id.*182:9-17. As to the materials Lilly already produced, Nektar raised concerns in interrogatory responses about [redacted]. ECF 210-44 at 5-6. These concerns were baseless. Lilly had diligently worked to transfer these materials as quickly as possible while maintaining open communication with Nektar regarding the anticipated costs and timeline of the transfer. *See* ECF 210-68 at 3. The parties worked together on the transfer, which Nektar admitted was "[redacted]" and that it had "[redacted]" about Lilly's efforts. ECF 210-45, 2; ECF 210-5 at 170:17-171:7, 183:4-13.

Second, the Agreement does not establish a strict [redacted] deadline for the transfer of Rezpeg-related materials. Nektar relies on §11.2, which requires Lilly to provide "[redacted]" upon termination. ECF 210-2 §11.2. Although this provision mentions that during this notice period after termination "the parties shall cooperate in the wind down of applicable activities under this Agreement," this language does not require that the post-termination transfer be completed within that notice window. Instead, §11.4(b)(ii) separately addresses the transfer requirement, simply requiring that Lilly "reasonably cooperate with Nektar to facilitate a smooth, orderly and [redacted] transition (including during any notice period hereunder) of any ongoing Product development activities." *Id.* §11.4(b)(ii). The clause specifically contemplates that the transition period may "include[]"—but is not limited to—the [redacted] making clear that Nektar's suggestion of a strict [redacted] clock is incorrect.

Third, Nektar has often admitted to the lack of harm from this theory. Its own contemporaneous documents concede that "[redacted]" ECF 210-45 at 2. Nektar could not say how any purportedly missing documents would be "[redacted]" to its development of Rezpeg. ECF 210-5 at 181:6-182:8. And it could not even explain how it "[redacted]." *Id.* These defects will preclude Nektar from proving any conduct by Lilly caused damages—a dispositive element of this claim.

V. NEKTAR CANNOT PROVE ANY BREACH OF THE IMPLIED COVENANT AT TRIAL.

The implied covenant of good faith and fair dealing "is breached when a party acts in a manner that deprives the other party of the benefits of the contract." *Parlux Fragrances, LLC v. S. Carter Enters.,*

LLC, 163 N.Y.S.3d 108, 123 (N.Y. App. Div. 2022). Nektar's claim for breach of the implied covenant fails for the same reasons as its breach of contract claims. Nektar relies on the same underlying facts in pursuit of both types of claims. *See* ECF 210-44 at 7 [redacted] (emphasis added). This duplicative claim is an improper attempt to "add to, detract from, or alter the terms of the contract itself." *Warner Theatre Assocs. L.P. v. Metro. Life Ins. Co.*, 1997 WL 685334, at *6 (S.D.N.Y. Nov. 4, 1997), *aff'd*, 149 F.3d 134 (2d Cir. 1998).

VI. CONCLUSION

For the reasons explained above, Nektar will be unable to succeed on its breach of contract or breach of the implied covenant of good faith and fair dealing claims.

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Respectfully submitted,

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